Nova Spine LLC

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PO Box 969
Elmsford, NY 10523

510(k) Summary of Safety and Effectiveness
Safe Medical Devices Act of 1990 (SMDA)
510(k) Summary

OCT 16 2006

Date prepared:	September 27, 2006
Name of Firm:	NovaSpine LLC 15 Heritage Court Tarrytown, NY 10591 Telephone: 914-909-6577 Fax: 914-909-6577 E-mail : hkhosrow@optonline.net
510(k) Contact:	Dina L. Weissman, J.D. P.O. Box 205 Derby CT 06418 Telephone: (203) 736-8631 Email: dina.weissman@sbcglobal.net
Manufacturer:	Asskea (Simex) Medizintechnik, GmbH Schlefweg 25, D-99718, Greussen, Germany
Trade Name:	**NovaSpine Powered Suction Pump PRO-I**
Common Name:	Powered Suction Pump
Classification:	FDA 21 CFR 878.4780 Powered Suction Pump Class II, Code: BTA
Device Product Code	BTA - Pump, Portable, Aspiration, (Manual or Powered)
Substantial Equivalency	**Kinetic Concepts** K971548 "AmbuVAC" **Blue Sky Medical Group, Inc.** K042134 "Versatile 1 Wound Vacuum System" **NovaSpine LLC** K061133 "SIMEX Suction Pump"
Indications for Use	The NovaSpine Powered Suction Pump PRO-I is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

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Device Description:

The NovaSpine Powered Suction Pump PRO-I is a lightweight, self contained, portable battery powered, aspiration pump for medical suction procedures where secretions, blood and other body fluids must be removed through the application of continuous or intermittent negative pressure. The NovaSpine Powered Suction Pump PRO-I is available in only one model:

Table 1

1.	Suction:	9 liters/min,
2.	Maximum Vacuum:	200 mmHg
3.	Noise:	35 dba,
4.	Weight:	2.8 kg
5.	Operation:	Continuous and Intermittent
6.	Dimensions:	290mmX359mmX130mm

The pump is powered with a rechargeable Nickel-metal Hydride (NiMh) battery. The unit includes a port for an external power supply and/or a battery charger.

The NovaSpine Powered Suction Pump PRO-I is composed of two parts:

1. The pump and battery pack are all housed in a single unit. The charging unit is a separate stand alone device.

2. The consumable/disposable components such as:
    a. Collection canister (secretion container),
    b. Related hoses (tubing)
    c. Hose connectors
    d. Filters
    e. Other accessories as detailed in the operating manual

Basis For Substantial Equivalence:

This product is substantially equivalent to similar devices with similar technical specifications currently on the market such as:

Kinetic Concepts K 971548 AmbuVAC
Blue Sky Medical Group, Inc. K042134 Versatile 1 Wound Vacuum System
NovaSpine, LLC K061133 SIMEX Suction Pump

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR -7 2009

NovaSpine, LLC
% Weissman Law Firm
Ms. Dina L. Weissman, J.D.
P.O. Box 205
Derby, Connecticut 06418

Re: K062456
Trade/Device Name: NovaSpine Powered Suction Pump PRO-1
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 18, 2006
Received: August 23, 2006

Dear Ms. Weissman:

This letter corrects our substantially equivalent letter of December 16, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K062456

Device Name:

NovaSpine Powered Suction Pump PRO-I

Indication for Use:

The NovaSpine Powered Suction Pump PRO-I is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062456